PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	07.05.2002
Applicant's or agent's file reference 110/01507	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00471	03/08/2000	27/01/2000

Applicant
DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
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Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
110/01507		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IL00/00471	03/08/2000	27/01/2000
International Patent Classification (IPC) or national classification and IPC A61B17/70		
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27/08/2001	07.05.2002
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Josten, S Telephone No. +49 89 2399 2338

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IL00/00471

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-27	as originally filed			

Claims, No.:

7-119	as received on	18/04/2002	with letter of	15/04/2002
1-6	with telefax of	25/04/2002		

Drawings, sheets:

1/13-13/13	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 107, 113-119.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2-4 are so unclear that no meaningful opinion could be formed (*specify*):
   see separate sheet

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 107, 113-119.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1, 5-106.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1, 5-106
Industrial applicability (IA)	Yes:	Claims	1, 5-106
	No:	Claims	

2. Citations and explanations
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. No international search report has been established for the **amended** claim 107, for **method claims** 113 and 114 and for **claims** 115 to 119 which did not form part of the originally filed set of claims. For this reason claims 107 and 113 to 119 will not be examined.

2. Claims 2 to 4 each are not clear as to the wording that "said implant is adapted to anchor in a non-axial orientation in a bone". At present it appears that this wording intends to define the position of the implant in a bone thus relating to the use of the implant but not to a technical feature of the implant per se.

Re Item IV

Lack of unity of invention

3. This International Preliminary Examining Authority considers that there are the following **2** inventions claimed in the international application:

   a) the **implant** according to claim 1, followed by dependent claims 2 to 106, and
   b) the **inline pressure gauge** according to independent claim 108, followed by dependent claims 109 to 112.

   These **2** inventions are not so linked that they form a single general inventive concept. The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. However, in the present case there are no common features in independent claims 1 and 108. Consequently, there is no common concept linking these claims.

   Thus, the application does not comply with the requirements of unity of invention (Rule 13.1 PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

4. Present claim 1 contains at least the following two alternatives:
a) the implant according to the features depicted in lines 3 to 7 combined with feature (a) **or**
b) the implant according to the features depicted in lines 3 to 7 combined with feature (b).
Reference is made to the fact that a claim containing several alternatives does not meet the requirements of the PCT if at least one of said alternatives already does not meet these requirements.

5. As to the first alternative a) of present claim 1 the document US-A-5827289 (=**D1**) is considered to represent the closest prior art. Figure 18 of **D1** discloses an implant adapted to anchor in cancellus bone (see **D1**, column 15, lines 60 to 63; see Figure 18 showing the cancellus bone 168 and the cortical bone 173), comprising:
a shaft 177 having a longitudinal axis and defining an inflation lumen therethrough; and
at least one inflatable anchor portion 166 connected to said lumen, whereby inflation of said anchor portion causes said implant to engage said cancellus bone (see column 15, lines 60 to 63), wherein said anchor is adapted for engaging said canellus bone,
(the anchor portion) including a plurality of protrusions (i.e. a first protrusion between the meshes 170 and 170a and a second protrusion above the mesh 170) that are non-axial to said shaft axis and adapted to engage canellus bone (see Figure 18).

Thus, the first alternative of claim 1 is not novel and does not meet the requirements of Article 33(2) PCT.

6. As to the second alternative b) of present claim 1 the document **D1** is also considered to represent the closest prior art. **D1** (see Figure 17A or Figure 18)

discloses all the features depicted in lines 3 to 7 of present claim1 (see the above-mentioned paragraph 5).

The subject-matter of the second alternative of present claim 1 differs from the implant known from **D1** in the feature that (b) the anchor portion comprises less than 30% of a lenth of said implant. By means of this differentiating feature the problem is solved to provide an implant having a compact anchor portion which is effective over a limited region only.

However, the man skilled in the art knows from the document US-A-5578035 (=**D2**), that a compact anchor portion being effective over a limited region can be achieved by an implant having an anchor portion which extends over less than 30% of the length of the implant (see figures 2a, 2b, 3 and 4 of **D2**). Thus, in order to solve the problem posed the man skilled in the art would include this feature known from **D2** in the implant known from **D1** thus arriving at the subject-matter of present claim 1.

The second alternative of present claim 1 therefore does not involve an inventive step and does meet the requirements of Article 33(3) PCT.

7. In view of the documents cited in the Search Report the dependent claims 5 to106 cannot be seen as involving an inventive step (Article 33(3) PCT) since the features of those claims relate to slight constructional changes which come within the scope of the customary practice followed by persons skilled in the art.

CLAIMS

1. An implant adapted to anchor in cancellus bone, comprising:

a shaft having a longitudinal axis and defining an inflation lumen therethrough; and

at least one inflatable anchor portion connected to said lumen, whereby inflation of said anchor portion causes said implant to engage said cancellus bone, wherein said anchor is adapted for engaging said cancellus bone having at least one of:

(a) including a plurality of protrusions that are non-axial to said shaft axis and adapted to engage cancellus bone; and

(b) the anchor portion comprises less than 30% of a length of said implant.

2. An implant according to claim 1, wherein said implant is adapted to anchor in a non-axial orientation in a bone, wherein said non-axial orientation comprises an angle of at least 30° to the axis.

3. An implant according to claim 1, wherein said implant is adapted to anchor in a non-axial orientation in a bone, wherein said non-axial orientation comprises an angle of at least 50° to the axis.

4. An implant according to claim 1, wherein said implant is adapted to anchor in a non-axial orientation in a bone, wherein said non-axial orientation comprises an angle of at least 70° to the axis.

5. An implant according to any of claims 1-4, wherein the anchor portion comprises less than 60% of a length of said implant.

6. An implant according to any of claims 1-4, wherein the anchor portion comprises less than 50% of a length of said implant.

7. An implant according to any of claims 1-4, wherein the anchor portion comprises less than 30% of a length of said implant.

8. An implant according to any of claims 1-7, wherein the implant has a length less than 30% of a length of a maximal extent of a bone for which said implant is designed.

9. An implant according to any of claims 1-7, wherein the implant has a length less than 20% of a length of a maximal extent of a bone for which said implant is designed.

10. An implant according to any of claims 1-7, wherein the implant has a length less than 10% of a length of a maximal extent of a bone for which said implant is designed.

11. An implant according to any of claims 1-10, wherein said anchor portion is at a distal tip of said shaft.

12. An implant according to claim 11, comprising a distal end adapted for insertion through cancellus bone.

13. An implant according to any of claims 1-10, wherein said anchor portion is at a proximal tip of said shaft.

14. An implant according to any of claims 1-10, wherein said anchor portion is at a center portion of said shaft.

15. An implant according to claim 14, wherein said shaft has at least one end adapted to attach an object thereto.

16. An implant according to claim 14, wherein said shaft has two ends each adapted to attach an object thereto.

17. An implant according to any of claims 1-14, comprising a base portion having a greater diameter than said shaft and adapted to remain outside said bone.

18. An implant according to claim 17, wherein said base is adapted to urge an object against an outside of said bone.

19. An implant according to claim 18, wherein said object comprises a bone plate.

20. An implant according to claim 17, wherein said base is adapted for attachment of an object thereto.

21. An implant according to claim 20, wherein said object comprises a rod.

22. An implant according to claim 21, wherein said rod has a thin surface texture.

23. An implant according to claim 21, wherein said surface texture comprises a plurality of radial notches.

24. An implant according to any of claims 1-14, comprising a base portion having a diameter that is not greater than said shaft and adapted to remain inside said bone.

25. An implant according to any of claims 1-14, comprising a separate axial over tube adapted to be fixed to said bone and sized to enclose said shaft.

26. An implant according to claim 25, wherein said shaft is free to move axially in said tube.

27. An implant according to claim 25, wherein said shaft is elastically axially coupled to said tube.

28. An implant according to claim 25, wherein said shaft is rigidly coupled to said tube.

29. An implant according to any of claims 1-28, comprising a second shaft having at least a second inflatable anchor portion defined thereon and comprising a coupling between said shaft and said second shaft.

30. An implant according to claim 29, wherein said second shaft is adapted for axial inserting in said bone.

31. An implant according to claim 29 or claim 30, wherein said coupling comprises a through hole in said second shaft.

32. An implant according to claim 29 or claim 30, wherein said coupling comprises a through hole in said shaft.

33. An implant according to claim 29 or claim 30, wherein said coupling comprises a notch in said second shaft.

34. An implant according to any of claims 29-33, comprising a strut adapted to couple to said first and second shafts.

35. An implant according to any of claims 1-33, comprising a strut adapted to at least contact said shaft.

36. An implant according to claim 35, wherein said strut is coupled to said shaft.

37. An implant according to any of claims 1-36, wherein said inflatable anchor portions is adapted to expand wholly in cancellus bone and not contact cortical bone.

38. An implant according to any of claims 1-37, comprising an expanding cortical anchoring portion, adapted to expand in contact with cortical bone.

39. An implant according to any of claims 1-38, comprising a second inflatable cancellus anchoring portion, adapted to engage a cancellus bone portion of another section of said bone, separated by a fracture line from a section which anchors said anchoring portion.

40. An implant according to any of claims 1-39, wherein said shaft is not inflatable.

41. An implant according to any of claims 1-39, wherein said shaft inflates to a lesser degree than said anchoring portion.

42. An implant according to any of claims 1-41, wherein at least part of said shaft is externally threaded.

43. An implant according to claim 42, wherein said threading is adapted to engage cortical bone.

44. An implant according to claim 42, wherein said threading is adapted to engage cancellus bone.

45. An implant according to any of claims 1-44, wherein at least part of said anchoring portion is externally threaded.

46. An implant according to claim 45, wherein said anchoring portion threading is damaged by said inflation.

47. An implant according to claim 45, wherein said anchoring portion threading is not damaged by said inflation.

48. An implant according to any of claims 1-47, comprising matched threading on said anchoring portion and said shaft.

49. An implant according to any of claims 1-48, comprising a source of pressurized fluid for inflating said inflatable portion.

50. An implant according to claim 49, wherein said fluid comprises a saline solution.

51. An implant according to claim 49, wherein said fluid hardens after said inflation.

52. An implant according to any of claims 1-51, wherein said inflation elastically deforms said inflatable portion.

53. An implant according to any of claims 1-51, wherein said inflation plastically deforms said inflatable portion.

54. An implant according to any of claims 1-53, wherein said shaft and said inflatable portion are comprised of a metal.

55. An implant according to claim 54, wherein said metal comprises stainless steel.

56. An implant according to claim 54, wherein said metal comprises titanium.

57. An implant according to any of claims 1-56, wherein said shaft and said inflatable portion are comprised of a same material.

58. An implant according to any of claims 54-57, wherein at least a part of said inflatable portion is metallurgically treated to have better elongation properties than said shaft.

59. An implant according to any of claims 1-56, wherein said shaft and said inflatable portion are comprised of different materials.

60. An implant according to any of claims 1-59, wherein said shaft defines a guide channel for a guiding element.

61. An implant according to claim 60, wherein said guiding element is a guide wire.

62. An implant according to claim 60, wherein said guiding element is a rigid element.

63. An implant according to any of claims 59-62, wherein said guide channel comprises a lumen.

64. An implant according to any of claims 59-62, wherein said guide channel comprises a slot along an exterior part of said shaft.

65. An implant according to any of claims 1-64, wherein said inflatable portion comprises a thin membrane.

66. An implant according to claim 65, wherein said inflatable portion comprises a plurality of protrusions on said membrane.

67. An implant according to claim 66, wherein said plurality of protrusions comprises at least one axially aligned bar.

68. An implant according to claim 66 or claim 67, wherein said plurality of protrusions comprises at least one trans-axially aligned bar.

69. An implant according to any of claims 66-68, wherein said plurality of protrusions comprises a spirally arranged bar.

70. An implant according to any of claims 66-69, wherein said plurality of protrusions comprises a mesh pattern.

71. An implant according to any of claims 66-70, wherein said plurality of protrusions comprises an array arrangement of protrusions.

72. An implant according to any of claims 65-71, wherein said membrane has a smooth surface texture.

73. An implant according to any of claims 65-71, wherein said membrane has a rough surface texture.

74. An implant according to any of claims 65-71, wherein said protrusions resist bending of said inflatable portion.

75. An implant according to any of claims 65-71, wherein said protrusions resist bending of said inflatable portion relative to said shaft.

76. An implant according to any of claims 1-75, wherein said inflatable portion and said shaft have substantially a same diameter prior to inflation.

77. An implant according to any of claims 1-75, wherein said inflatable portion has a substantially smaller diameter than said shaft prior to inflation.

78. An implant according to any of claims 1-75, wherein said inflatable portion has a substantially greater diameter than said shaft prior to inflation.

79. An implant according to any of claims 1-78, wherein said implant has a length of less than 150 mm.

80. An implant according to any of claims 1-78, wherein said implant has a length of less than 100 mm.

81. An implant according to any of claims 1-78, wherein said implant has a length of less than 75 mm.

82. An implant according to any of claims 1-78, wherein said implant has a length of less than 50 mm.

83. An implant according to any of claims 1-78, wherein said implant has a length of less than 30 mm.

84. An implant according to any of claims 1-83, wherein said implant has a shaft diameter of less than 15 mm.

85. An implant according to any of claims 1-83, wherein said implant has a shaft diameter of less than 10 mm.

86. An implant according to any of claims 1-83, wherein said implant has a shaft diameter of less than 5 mm.

87. An implant according to any of claims 1-83, wherein said implant has a shaft diameter of less than 3 mm.

88. An implant according to any of claims 1-87, wherein said implant has an expansion ratio of at least 1:1.2 of its diameter before and after inflation.

89. An implant according to any of claims 1-87, wherein said implant has an expansion ratio of at least 1:1.4 of its diameter before and after inflation.

90. An implant according to any of claims 1-87, wherein said implant has an expansion ratio of at least 1:1.7 of its diameter before and after inflation.

91. An implant according to any of claims 1-87, wherein said implant has an expansion ratio of at least 1:2.2 of its diameter before and after inflation.

92. An implant according to any of claims 1-87, wherein said implant has an expansion ratio of at least 1:3 of its diameter before and after inflation.

93. An implant according to any of claims 1-92, wherein said implant has an expansion ratio of at most 1:5 of its diameter before and after inflation.

94. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 15 PSI.

95. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 50 PSI.

96. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 75 PSI.

97. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 100 PSI.

98. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 200 PSI.

99. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 400 PSI.

100. An implant according to any of claims 1-93, wherein said implant is adapted to withstand an inflation pressure of at least 700 PSI.

101. An implant according to any of claims 1-100, wherein said implant is sterilized.

102. An implant according to any of claims 1-101, wherein said implant is provided in a sterile packaging including an indication of a use of said implant.

103. An implant according to claim 1, wherein said implant is adapted for use as a pedicle anchoring screw.

104. An implant according to claim 1, wherein said implant is adapted for use as a compression hip nail.

105. An implant according to claim 1, wherein said implant is adapted for use as a dynamic hip nail.

106. An implant according to claim 1, wherein said implant is adapted for joining fractures of condyles.

107. A hip implant comprising:

a hip joint section; and

an inflatable femur shaft anchor, adapted to engage an inside of a femoral shaft, said shaft anchor comprising a surface membrane having at least one protrusion.

108. An inline pressure gauge for a fluid pump, comprising:

a lumen containing a fluid under pressure;

a piston which advances to increase a pressure of said fluid, said piston defining a sensing lumen;

a marker plug in communication with said sensing lumen, axially disposed in said piston and having an axial resistance, such that an axial position of said marker plug represents said pressure of said fluid.

109. A gauge according to claim 108, wherein said piston defines at least one viewing aperture overlying said marker plug, for viewing said axial position of said plug.

110. A gauge according to claim 108 or claim 109, wherein said piston is advanced using a thread-type lever.

111. A gauge according to any of claims 108-110, wherein said pressure is at least 70 PSI.

112. A gauge according to any of claims 108-110, wherein said pressure is at least 250 PSI.

113. A method of treating a fracture in a non-shaft portion of a bone, comprising:

inserting an inflatable nail into said bone through two parts of the bone separated by the fracture, at a non-axial direction thereto; and

inflating said nail such that said nail engages at least one cancellus portion of said bone.

114. A method of anchoring an object to a bone, comprising:

inserting an inflatable anchor into a cancellus portion of said bone;

inflating said anchor such that said anchor engages said cancellus portion of said bone; and

attaching said object to said anchor.

115. An implant according to claim 107, wherein said at least one protrusion is on an external surface of said membrane.

116. An implant according to claim 107 or claim 115, wherein said at least one protrusion comprises a bar.

117. An implant according to claim 107 or claim 115, wherein said at least one protrusion comprises a bump.

118. An implant according to claim 107 or claim 115, wherein said at least one protrusion comprises a spiral bar.

119. An implant according to any of claims 107 or 115-118, wherein said at least one protrusion is adapted to engage an inside of a femur.